JUN 2 7 2002

K013613

510-528 S. Vermont Avenue Glendora, CA 91741 (626) 914-2891 FAX (626) 914-2285

510(k) SUMMARY

Date Submitted: June 25, 2002

By: Oasis Medical, Inc.
514 S. Vermont Avenue
Glendora, CA 91741

Contact Person: Yvonne Fernandez

Trade Name: Soft Plug® Absorbable Plugs – SA

Common Name: Intracanalicular Plug/Punctum Plug

Classification Name/Product Code: Punctum Plug/86LZU

Soft Plug® Absorbable Plugs – SA

The proposed device, the Soft Plug® Absorbable Plugs – SA, is substantially equivalent in intended use and operation to the various collagen intracanalicular plugs in the market today. These include the Soft Plug® Collagen Intracanalicular Plug by OASIS Medical (K946357), the Temporary Intracanalicular Plug by Eagle Vision (K890919), and the Collagen Implants For Use in the Lacrimal Efficiency Test™ by Lacrimedics (K895342). All of these plugs are 2 mm long and are cut from non-sterile suture material. The implants are intended to be inserted into the canaliculus to block fluid flow for a temporary period of time (less than 3 months based on results obtained in an animal study) until they are absorbed. The only difference is the type of absorbable suture they are cut from, polyglyconate versus collagen, and the length of time they will take to absorb, less than 3 months versus several days.

The proposed device, the Soft Plug® Absorbable Plugs – SA, is also similar in intended use and operation to the Herrick Lacrimal Plug™ by Lacrimedics (K896175). This is a silicone intracanalicular plug intended for insertion into the canaliculus to permanently block fluid flow. It approximates the size of the absorbable plugs mentioned above.

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Pre-clinical testing on polyglyconate suture produced no evidence of antigenicity, systemic toxicity, carcinogenicity, mutagenicity, tetratogenicity, or adverse effects on reproductive performance. Polyglyconate plugs inserted into the rabbit canaliculus remained in place for two months. By the third month, all of the plugs were gone from the canaliculus. This residency time falls between the absorbable collagen plugs, which are several days, and the Herrick plug, which is designed to remain permanently in the canaliculum.

A double-blind study involving 40 dry-eye patients was conducted which compared a Soft Plug® Absorbable Plugs – SA placed in the lower canaliculus of one eye to a collagen plug placed in the lower canaliculus of the other eye. Each patient was evaluated at the start of the study and again at monthly intervals over a period of four months.

None of the plugs were removed. There were no complications or adverse events. All of the patients showed signs of improvement as a result of the treatment. Most patients were unable to differentiate between the Soft Plug® Absorbable Plugs – SA and the collagen plug and reported the same comfort level for both eyes during the monthly examinations. In the clinical study, the subjective relief achieved from both plugs persisted for at least one month.

Yvonne Fernandez

6/25/02
date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Oasis Medical, Inc.
c/o Ms. Yvonne Fernandez
Director, RA/QA
514 South Vermont Avenue
Glendora, CA 91741

Re: K013613
Trade/Device Name: Soft Plug® Absorbable Intracanalicular Implants - SA
Regulation Name: Plug, punctum
Regulatory Class: Unclassified
Product Code: LZU
Dated: March 29, 2002
Received: April 2, 2002

Dear Ms. Fernandez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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OASIS Medical, Inc.
Soft Plug® Absorbable Plugs – SA
Indications For Use

510(k) Number K013613

Device Name: Soft Plug® Absorbable Plugs – SA

Indications for Use:

The OASIS Medical Soft Plug® Absorbable Plug – SA is intended for temporary use in patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching or foreign body sensations which can be relieved by blockage of the canaliculus. It may be used in the treatment of dry eye syndrome and the dry eye components of various ocular surface diseases. When indicated, the OASIS Medical Soft Plug® Absorbable Plug – SA may be used after surgery of the eye to prevent complications due to dry eye and to enhance the retention of ocular medications on the eye.

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K013613

Prescription Use: X OR Over The Counter Use: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)